REMARKS

Applicant respectfully requests reconsideration and allowance of the subject application. Claims 1-2, 4-5, 7-9, 11, 16, 21-23, and 71-74 are pending examination.

Rejections under 35 U.S.C. §102(b)

The Office rejects claims 1-2, 4-5, 7-9, 11, 16, 21-23, 28, and 71-74 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,759,822 to Chenchik et al. (the "Chenchik reference" or "Chenchik"). Of these rejected claims, claim 28 has been cancelled.

The Office also rejects claims 1-2, 4-5, 8, 23, and 71-72 under 35 U.S.C. §102(b) as being anticipated by Legal et al., Vet. Res. (2000) 31:565-572, (the "Legay reference" or "Legay").

Neither Chenchik nor Legay show or disclose "synthesizing" as described by the Applicant, or synthesizing a "clinically relevant" "reference nucleic acid" as described by Applicant. That is, neither cited reference shows or discloses synthesizing an artificial base sequence in a base by base manner, such that the reference nucleic acid produced is in essence clinically relevant, and in the same base by base synthesis, creating one or more primer targets in the artificial base sequence for purposes of amplification.

Nonetheless, to move prosecution forward, the Applicant amends claims to more particularly point out and distinctly claim the subject matter. The amendments are actually not meant to narrow the scope of the claims, but rather to

define in the claims the manner in which Applicant describes "synthesizing," "reference nucleic acid," and "clinically relevant" in the specification.

Claim 1

Claim 1, as amended, defines a method of creating a pure clinical reference solution for testing multiple genetic conditions, wherein the clinical reference solution is substantially free of clinically irrelevant nucleic acid detrimental to the testing, including:

- determining one or more clinically relevant sites on one or more nucleic acid sequences;

- for each clinically relevant site, designing an arrangement of bases to emulate the clinically relevant site as isolated from adjacent clinically irrelevant nucleic acid, wherein the arrangement of bases also includes one or more primer targets;

- synthesizing, base by base, a single-stranded artificial version of each arrangement of bases associated with each clinically relevant site; and

- mixing each artificial version of a clinically relevant site into a single solution.

The Chenchik and Legay references, on the other hand, do not show or disclose each element of Applicant's claim 1. For example, the Chenchik and Legay references do not show or disclose "designing an arrangement of bases to emulate the clinically relevant site as isolated from adjacent clinically irrelevant nucleic acid" or "synthesizing, base by base, a single-stranded artificial version of each arrangement of bases associated with each clinically relevant site," etc.

Chenchik and Legay merely describe conventional methods of amplifying large DNA fragments and creating plasmids, etc., wherein much of the nucleic acid content is bulky filler—clinically irrelevant nucleic acid material that is extraneous and detrimental to combining multiple nucleic acid references in a single reference solution. In other words, many of the clinically relevant sites desirable for a clinical reference solution are mutations. The extraneous nucleic acid material inherent in these conventional methods dilutes the identification of mutations. This is because with a conventional technique, the species in the reference solution is not substantially the pure mutation site, but rather very large nucleic acid fragments of which only a tiny proportion is the region of clinical interest. Worse yet, when a conventional technique tries to combine two or more types of clinical tests into a single reference solution, the identification of each mutation becomes highly diluted (by the extra irrelevant material), or in most cases, the combination does not work at all.

Applicant's claim 1 recites synthesis of the pure mutation sites only, "per se," connected directly and seamlessly with a primer target during the same base by base synthesis. The result is nucleic acid sequences of very small footprint,

each nucleic acid sequence being a substantially pure region of clinical interest *only*. Such artificial versions of clinically relevant nucleic acid sites can coexist in a reference solution without significantly occluding each other and without diluting identification of mutations, even though numerous different sequences for multiple tests are represented in the same solution. This is quite different than Chenchik and Legay, where a first clinically relevant site exists on one side of a large fragment or plasmid, a second clinically relevant site would have to exist on a different side of a different large fragment or plasmid, thus rendering such a conventional attempt unworkable. Applicant's claim 1 has the effect of conceptually isolating the clinically relevant segments from a larger sequence and synthesizing them with relevant tags, thus producing reference solutions in which the clinically relevant species are small, pure, undiluted, essential, and without interference from filler.

Since the Chenchik and Legay references do not show or disclose each element of Applicant's claim 1, the 35 U.S.C. §102(b) rejections fail. Applicant respectfully submits that claim 1 is allowable over Chenchik and Legay.

Claims 2, 4-5, 7-9, 11, 16, 21-23

For at least the reasons set forth above with respect to claim 1, Applicant submits that dependent claims 2, 4-5, 7-9, 11, 16, 21-23 are also allowable over the Chenchik and Legay references. Dependent claims contain the language of the claims from which they depend. Claims 2, 4-5, 7-9, 11, 16, 21-23 depend from claim 1, therefore these claims should also be allowable.

Claim 71

Claim 71, as amended, defines a method, including:

- designing multiple reference nucleic acids, wherein each reference nucleic acid comprises an arrangement of bases emulating a clinically relevant site of a human nucleic acid exclusive of clinically irrelevant human nucleic acid adjacent to the clinically relevant site;

- synthesizing, base by base for each reference nucleic acid, a first mixture of various of the reference nucleic acids, wherein each of the various reference nucleic acids in the first mixture includes one or more tags allowing PCR amplification of the first mixture via a primer set specific to the tags of the first mixture; and

- synthesizing, base by base for each reference nucleic acid, a second mixture of various of the reference nucleic acids, wherein each of the various reference nucleic acids in the second mixture includes one or more tags allowing PCR amplification of the second mixture via a second primer set specific to the tags of the second mixture.

Claim 71 defines a technique of synthesizing different primer targets (tags) onto different clinically relevant base sequences or onto different sets of the clinically relevant base sequences so that the different species, or different sets of species, can be differentially amplified. In other words, claim 71 recites relatively complete control over—"tuning of"—the presentation of each clinically relevant reference nucleic acid in a reference solution.

Similar to the reasons described above for claim 1, the Chenchik and Legay references do not show or disclose each element of Applicant's claim 71. For example, the Chenchik and Legay references do not show or disclose "designing...an arrangement of bases emulating a clinically relevant site of a human nucleic acid exclusive of clinically irrelevant human nucleic acid adjacent to the clinically relevant site" or "synthesizing, base by base...."

Since the Chenchik and Legay references do not show or disclose each element of Applicant's claim 71, the 35 U.S.C. §102(b) rejections fail. Applicant therefore respectfully submits that claim 71 is allowable over the Chenchik and Legay references.

Claims 72-74

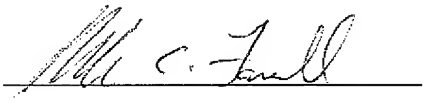
For at least the reasons set forth above with respect to claim 71, Applicant submits that dependent claims 72-74 are also allowable over the Chenchik and Legay references. Dependent claims contain the language of the claims from which they depend. Claims 72-74 depend from claim 71, therefore these claims should be allowable too.

Conclusion

The Applicant submits that all of the remaining claims are in condition for allowance and respectfully requests such allowance. If unresolved issues remain, Applicant respectfully requests that the undersigned attorney be contacted for scheduling an interview.

Respectfully Submitted,

Dated: 9-21-06

By: 

Mark Farrell
Lee & Hayes, PLLC
Reg. No. 45,988
Attorney for Applicant
Telephone: 509-324-9256 x243
Facsimile: (509) 323-8979